PCO_2 AND CALCULATED VALUES FOR HCO_3, BASE EXCESS AND ANION GAP

PCO_2 is measured by direct potentiometry. In the calculation of results for ***P***CO_2, concentration is related to potential through the Nernst equation. Results are measured at 37°C when using cartridges that require thermal control and corrected to 37°C when using cartridges that do not require thermal control.

Calculated Values

When a cartridge includes sensors for both pH and ***P***CO_2, bicarbonate (HCO_3), total carbon dioxide (TCO_2) and base excess (BE) are calculated.[1]

$\log HCO_3 = pH + \log PCO_2 - 7.608$

$BE_{ecf} = HCO_3 - 24.8 + 16.2\ (pH - 7.4)$

$BE_b = (1 - 0.014*Hb) * [\ HCO_3 - 24.8 + (1.43 * Hb + 7.7) * (pH - 7.4)\ ]$

Anion Gap is calculated in the EC8+ and CHEM8+ catridges as follows:

Anion Gap (EC8+) = $(Na + K) - (Cl + HCO_3)$

Anion Gap (CHEM8+) = $(Na + K) - (Cl + (TCO_2 - 1))$

See below for information on factors affecting results. Certain substances, such as drugs, may affect analyte levels *in vivo*.[2] If results appear inconsistent with the clinical assessment, the patient sample should be retested using another cartridge.

Intended Use

The test for ***P***CO_2, as part of the i-STAT System, is intended for use in the *in vitro* quantification of carbon dioxide partial pressure in arterial, venous, or capillary whole blood.

Contents

Each i-STAT cartridge contains one reference electrode (when potentiometric sensors are included in the cartridge configuration), sensors for the measurement of specific analytes, and a buffered aqueous calibrant solution that contains known concentrations of analytes and preservatives. For cartridges that contain a sensor for the measurement of ***P***CO_2, a list of reactive ingredients is indicated below:

Reactive Ingredient
Carbon Dioxide (CO_2)

Metrological Traceability

The i-STAT System test for carbon dioxide partial pressure measures carbon dioxide partial pressure in arterial, venous, or capillary whole blood (dimension kPa) for *in vitro* diagnostic use. ***P***CO_2 values assigned to i-STAT's controls and calibration verification materials are traceable to U.S. National Institute of Standards and Technology (NIST) standard reference materials via commercially available certified specialty medical gas standards. i-STAT System controls and calibration verification materials are validated for use only with the i-STAT System and assigned values may not be commutable with other methods. Further information regarding metrological traceability is available from i-STAT Corporation.

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Abbott Point of Care

Expected Values

Test/Abbreviation	Units*	Reportable Range	Reference Range (arterial)	Reference Range (venous)
Partial Pressure Carbon Dioxide/***P***CO_2	mmHg	5 – 130	35 – 45[3]	41 – 51
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
Bicarbonate/HCO_3	mmol/L	1.0 – 85.0	22 – 26**	23 – 28**
Base Excess/BE	mmol/L	(-30) – (+30)	(-2) – (+3)[3]	(-2) – (+3)[3]
Anion Gap/AnGap	mmol/L	(-10) – (+99)	10 – 20[3]	10 – 20[3]

*The i-STAT System can be configured with the preferred units.
**Calculated from Siggaard-Andersen nomogram.[4]

To convert ***P***CO_2 results from mmHg to kPa, multiply the mmHg value by 0.133.

The reference ranges programmed into the analyzer and shown above are intended to be used as guides for the interpretation of results. Since reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be determined for the population being tested.

Clinical Significance

PCO_2 along with pH is used to assess acid-base balance. ***P***CO_2 (partial pressure of carbon dioxide), the respiratory component of acid-base balance, is a measure of the tension or pressure of carbon dioxide dissolved in the blood. ***P***CO_2 represents the balance between cellular production of CO_2 and ventilatory removal of CO_2 and a change in ***P***CO_2 indicates an alteration in this balance. Causes of primary respiratory acidosis (increase in ***P***CO_2) are airway obstruction, sedatives and anesthetics, respiratory distress syndrome, and chronic obstructive pulmonary disease. Causes of primary respiratory alkalosis (decreased ***P***CO_2) are hypoxia (resulting in hyperventilation) due to chronic heart failure, edema and neurologic disorders, and mechanical hyperventilation.

HCO_3 (bicarbonate), the most abundant buffer in the blood plasma, is an indicator of the buffering capacity of blood. Regulated primarily by the kidneys, HCO_3 is the metabolic component of acid-base balance. Causes of primary metabolic acidosis (decrease in HCO_3) are ketoacidosis, lactate acidosis (hypoxia), and diarrhea. Causes of primary metabolic alkalosis (increase in HCO_3) are vomiting and antacid treatment.

Base excess of the extracellular fluid or standard base excess is defined as the concentration of titratable base minus the concentration of titratable acid when titrating the average intracellular fluid (plasma plus interstitial fluid) to an arterial plasma pH of 7.40 at ***P***CO_2 of 40 mmHg at 37°C. Excess concentration of base in the average ECF remains virtually constant during acute changes in the ***P***CO_2 and reflects only nonrespiratory component of pH-disturbances.

Anion gap is reported as the difference between the commonly measured cations sodium and potassium and the commonly measured anions chloride and bicarbonate. The size of the gap reflects unmeasured cations and anions and is therefore an analytical gap. Physiologically, a deficit of anions cannot exist. While relatively nonspecific, anion gap is useful for the detection of organic acidosis due to an increase in anions that are difficult to measure. Anion gap can be used to classify metabolic acidosis into high and normal anion gap types. Anion gap may be only slightly increased in diarrhea and renal failure, but elevated (often >25) due to an increase in organic anions in lactic acidosis, ketoacidosis (alcoholic, diabetic, starvation) and uremia, an increase in inorganic anions in uremia, and an increase in anions from drugs such a salicylate and carbenicillin or toxins such as methanol and ethanol.

Temperature "Correction" Algorithm

PCO_2 is a temperature-dependent quantity and is measured at 37°C. The ***PC***O_2 reading at a body temperature other than 37°C can be 'corrected' by entering the patient's temperature on the chart page of the analyzer. See section 12 'Procedure for Cartridge Testing' in the i-STAT 1 System Manual or section 11 'Patient and Control Sample Testing' in the i-STAT System Manual for details. In this case, blood gas results will be displayed at both 37°C and the patient's temperature. The ***PC***O_2 at the patient's temperature (T_p) is calculated as follows[1]:

$$PCO_2(T_p) = PCO_2 \times 10^{0.019(T_p - 37)}$$

Note: Patient temperature corrected results are available only on cartridges containing pH, ***P***CO_2, and ***P***O_2 sensors.

Performance Characteristics

The performance characteristics of the sensors are equivalent in all cartridge configurations.

The typical performance data summarized below was collected in a health care facility by health care professionals trained in the use of the i-STAT System and comparative methods.

Precision data were collected in multiple sites as follows: Duplicates of each control fluid were tested in the morning and in the afternoon on five days for a total of 20 replicates. The averaged statistics are presented below.

Method comparison data were collected using CLSI guideline EP9-A[5]. Venous blood samples were collected in blood gas syringes. All samples were analyzed in duplicate on the i-STAT System and on the comparative methods within 10 minutes of each other. Arterial blood samples were collected from hospital patients in 3cc blood gas syringes and were analyzed in duplicate on the i-STAT System and the comparative method within 5 minutes of each other.

Deming regression analysis[6] was performed on the first replicate of each sample. In the method comparison table, n is the number of specimens in the data set, Sxx and Syy refer to estimates of imprecision based on the duplicates of the comparative and the i-STAT methods respectively, Sy.x is the standard error of the estimate, and r is the correlation coefficient.*

Method comparisons will vary from site to site due to differences in sample handling, comparative method calibration and other site specific variables.

* The usual warning relating to the use of regression analysis is summarized here as a reminder: For any analyte, "if the data is collected over a narrow range, the estimate of the regression parameters are relatively imprecise and may be biased. Therefore, predictions made from these estimates may be invalid".[7] The correlation coefficient, r, can be used as a guide to assess the adequacy of the comparative method range in overcoming this problem. As a guide, the range of data can be considered adequate if r>0.975.

Precision Data (mmHg)

Aqueous Control	Mean	SD	%CV
Level 1	63.8	1.57	2.5
Level 3	19.6	0.40	2.0

Method Comparison (mmHg)

	PCO_2 IL BGE	***P***CO_2 Radiometer ABL500
n	62	29
Sxx	0.69	0.74
Syy	1.24	0.53
Slope	1.003	1.016
Int't	-0.8	1.1
Sy.x	1.65	0.32
Xmin	30.4	28
Xmax	99.0	91
r	0.989	0.999

Factors Affecting Results*

Exposing the sample to air allows CO_2 to escape which causes ***P***CO_2 to decrease and pH to increase and HCO_3 and TCO_2 to be under-estimated. The use of partial-draw tubes (evacuated tubes that are adjusted to draw less than the tube volume, e.g. a 5 mL tube with enough vacuum to draw only 3 mL) is not recommended for use with the i-STAT System because of the potential for decreased measured ***P***CO_2 results and calculated HCO_3 and TCO_2 values. Under-filling blood collection tubes may also cause decreased ***P***CO_2 results. Care must also be taken to eliminate "bubbling" of the sample with a pipette when filling a cartridge to avoid the loss of CO_2 in the blood.

Allowing blood to stand (without exposure to air) before testing allows ***P***CO_2 to increase and pH to decrease, which will cause HCO_3 and TCO_2 to be over-estimated, due to metabolic processes.

For patients administered propofol (Diprivan®) or thiopental sodium (syn. thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutal, Pentothal Sodium®, Nesdonal Sodium®, Intraval Sodium®, Trapanal®, and Thiothal Sodium[7]), i-STAT recommends the use of G3+, CG4+, CG8+, EG6+ and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol (Diprivan®) or thiopental sodium.

* It is possible that other interfering substances may be encountered. These results are representative and your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

References

1. CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* CLSI document C46-A [ISBN 1-56238-444-9]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2001.

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990).

3. P.C. Painter, J.Y. Cope, J.L. Smith, "Reference Ranges, Table 41–20" in Tietz Textbook of Clinical Chemistry—Second Edition, C.A. Burtis and E.R. Ashwood, eds. (Philadelphia: W.B. Saunders Company, 1994).

4. E.L. Pruden, O. Siggaard-Andersen, and N.W. Tietz, Blood Gases and pH, in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood. (Philadelphia: W.B. Saunders Company, 1994).

5. CLSI. *Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.* CLSI document EP9-A [ISBN 1-56238-283-7]. CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 1995.

6. P.J. Cornbleet and N. Gochman, "Incorrect Least-Squares Regression Coefficients in Method-Comparison Analysis," Clinical Chemistry 25:3, 432 (1979).

7. The Merck Index, Eleventh Edition, Merck & Co., Inc., NJ 1989.

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